

Notice of Allowability

Application No.

09/895,263

Examiner

Phuong Huynh

Applicant(s)

HE ET AL.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/3/03.
2. ☒ The allowed claim(s) is/are 31-35,40-57,62-68,73-91 and 96-107.
3. ☒ The drawings filed on 07 February 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>1/5/04</u> |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Joseph Schuller on January 5, 2004.
3. **In the claims:**
 - 1-30. (Previously canceled)
 31. (Currently amended) An isolated antibody or fragment thereof that Specifically binds to a protein selected from the group consisting of:
 - (a) a protein consisting of amino acid residues 1 to 303 of SEQ ID NO:2;
 - (b) a protein consisting of amino acid residues 2 to 303 of SEQ ID NO:2;
 - (c) a protein consisting of amino acid residues 1 to 277 of SEQ ID NO:4 and
 - (d) a protein consisting of amino acid residues 2 to 277 of SEQ ID NO: 4
 32. (Previously presented) The antibody or fragment thereof of claim 31 that specifically binds protein (a).
 33. (Previously presented) The antibody or fragment thereof of claim 31 that specifically binds protein (b).
 34. (Previously presented) The antibody or fragment thereof of claim 31 that specifically binds protein (c).
 35. (Previously presented) The antibody or fragment thereof of claim 31 that specifically binds protein (d).
 - 36-39. (Previously canceled)

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40. (Previously presented) The antibody or fragment thereof of claim 31 that specifically binds protein (a) and protein (b).

41. (Previously presented) The antibody or fragment thereof of claim 31 that specifically binds protein (c) and protein (d).

42. (currently amended) The antibody or fragment thereof of claim 31 ~~which~~ wherein the antibody is a human antibody.

43. (currently amended) The antibody or fragment thereof of claim 31 ~~which~~ wherein the antibody is a polyclonal ~~antibody~~.

44. (currently amended) The antibody or fragment thereof of claim 31 ~~which~~ wherein the antibody is a monoclonal ~~antibody~~.

45. (Previously presented) The antibody or fragment thereof of claim 31 which is selected from the group consisting of:

- (a) a chimeric antibody;
- (b) a humanized antibody;
- (c) a single chain antibody; and
- (d) an Fab fragment.

46. (Currently amended) A labeled antibody or fragment thereof wherein the antibody or fragment thereof of claim 31 ~~wherein the antibody~~ is labeled.

47. (Currently amended) The labeled antibody or fragment thereof of claim 46 wherein the label is an enzyme.

48. (Previously presented) The antibody or fragment thereof of claim 31 wherein said antibody or fragment thereof specifically binds to said protein in an ELISA.

49. (Previously presented) An isolated cell that produces the antibody or fragment thereof of claim 31.

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50. (Previously presented) A hybridoma that produces the antibody of claim 31.

51. (Previously presented) A method of detecting an ICE-LAP 3 or 4 protein in a biological sample comprising:

- (a) contacting the biological sample with the antibody or fragment thereof of claim 31; and
- (b) detecting the ICE-LAP 3 or 4 protein in the biological sample.

52. (Currently amended) The method of claim 51 wherein the antibody or fragment thereof is a polyclonal ~~antibody~~.

53. (Currently presented) An isolated antibody or fragment thereof wherein the antibody is obtained from an animal that has been immunized with a protein comprising an amino acid

sequence selected from the group consisting of:

- (a) the amino acid sequence of amino acid residues 1 to 303 of SEQ ID NO:2;
 - (b) the amino acid sequence of amino acid residues 2 to 303 of SEQ ID NO:2;
 - (c) the amino acid sequence of amino acid residues 1 to 277 of SEQ m NO:4; and
 - (d) the amino acid sequence of amino acid residues 2 to 277 of SEQ m NO:4;
- wherein said antibody or fragment thereof specifically binds to said amino acid sequence.

54. (Currently presented) The antibody or fragment thereof of claim 53 wherein the antibody is obtained from an animal immunized with protein (a).

55. (Currently presented) The antibody or fragment thereof of claim 53 wherein the antibody is obtained from an animal immunized with protein (b).

56. (Currently presented) The antibody or fragment thereof of claim 53 wherein the antibody is obtained from an animal immunized with protein (c).

57. (Currently presented) The antibody or fragment thereof of claim 53 wherein the antibody is obtained from an animal immunized with protein (d).

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58-61. (Previously canceled)

62. (Currently amended) The antibody or fragment thereof of claim 53 ~~which wherein the antibody~~ is a monoclonal ~~antibody~~.

63. (Previously presented) The antibody or fragment thereof of claim 53 which is selected from the group consisting of:

- (a) a chimeric antibody;
- (b) a polyclonal antibody;
- (c) a humanized antibody;
- (d) a single chain antibody; and
- (e) an Fab fragment.

64. (Currently amended) An isolated antibody or fragment thereof that specifically binds to a protein selected from the group consisting of:

- (a) a protein consisting of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit Number 75875;
- (b) a protein consisting of the mature form of the polypeptide encoded by the cDNA contained in ATCC Deposit Number 75875;
- (c) a protein consisting of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit Number 75873; and
- (d) a protein consisting of the mature form of the polypeptide encoded by the cDNA contained in ATCC Deposit Number 75873 ÷ .

65. (Previously presented) The antibody or fragment thereof of claim 64 that specifically binds protein (a).

66. (Previously presented) The antibody or fragment thereof of claim 64 that specifically binds protein (b).

67. (Previously presented) The antibody or fragment thereof of claim 64 that specifically binds protein (c).

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68. (Previously presented) The antibody or fragment thereof of claim 64 that specifically binds protein (d).

69-72. (Previously canceled)

73. (Previously presented) The antibody or fragment thereof of claim 64 that specifically binds protein (a) and protein (b).

74. (Previously presented) The antibody or fragment thereof of claim 64 that specifically binds protein (c) and protein (d).

(75) (Currently amended) The antibody or fragment thereof of claim 64 ~~which~~ wherein the antibody is a human antibody.

76. (Currently amended) The antibody or fragment thereof of claim 64 ~~which~~ wherein the antibody is a polyclonal ~~antibody~~.

77. (Currently amended) The antibody or fragment thereof of claim 64 ~~which~~ wherein the antibody is a monoclonal ~~antibody~~.

78. (Previously presented) The antibody or fragment thereof of claim 64 which is selected from the group consisting of:

- (e) a chimeric antibody;
- (f) a humanized antibody',
- (g) a single chain antibody; and
- (h) an Fab fragment.

79. (Currently amended) A labeled antibody or fragment thereof wherein the antibody or fragment thereof of claim 64 ~~wherein the antibody~~ is labeled.

80. (Currently amended) The labeled antibody or fragment thereof of claim 79 wherein the label is an enzyme.

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81. (Previously presented) The antibody or fragment thereof of claim 64 wherein said antibody or fragment thereof specifically binds to said protein in an ELISA.

82. (Previously presented) An isolated cell that produces the antibody or fragment thereof of claim 64.

83. (Previously presented) A hybridoma that produces the antibody of claim 64.

84. (Previously presented) A method of detecting ICE-LAP 3 or 4 protein in a biological sample comprising:

(a) contacting the biological sample with the antibody or fragment thereof of claim 64; and

(b) detecting the ICE-LAP 3 or 4 protein in the biological sample.

85. (Currently amended) The method of claim 84 wherein the antibody or fragment thereof is a polyclonal ~~antibody~~.

86. (Currently amended) The method of claim 84 wherein the antibody or fragment thereof is a monoclonal ~~antibody~~.

87. (Currently presented) An isolated antibody or fragment thereof wherein the antibody is obtained from an animal that has been immunized with a protein comprising an amino acid sequence selected from the group consisting of:

(a) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit Number 75875;

(b) the amino acid sequence of the mature form of the polypeptide encoded by the cDNA contained in ATCC Deposit Number 75875;

(c) the amino acid sequence of the full-length polypeptide encoded by the cDNA contained in ATCC Deposit Number 75873; and

(d) the amino acid sequence of the mature form of the polypeptide encoded by the cDNA contained in ATCC Deposit Number 75873;

wherein said antibody or fragment thereof specifically binds to said amino acid sequence.

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88. (Currently presented) The antibody or fragment thereof of claim 87 wherein the antibody is obtained from an animal immunized with protein (a).

89. (Currently presented) The antibody or fragment thereof of claim 87 wherein the antibody is obtained from an animal immunized with protein (b).

90. (Currently presented) The antibody or fragment thereof of claim 87 wherein the antibody is obtained from an animal immunized with protein (c).

91. (Currently presented) The antibody or fragment thereof of claim 87 wherein the antibody is obtained from an animal immunized with protein (d).

92-95. (previously Canceled)

96. (Currently amended) The antibody or fragment thereof of claim 87 ~~which~~ wherein the antibody is a monoclonal antibody.

97. (Previously presented) The antibody or fragment thereof of claim 87 which is selected from the group consisting of:

- (a) a chimeric antibody;
- (b) a polyclonal antibody;
- (c) a humanized antibody;
- (d) a single chain antibody; and
- (e) an Fab fragment.

98. (Previously presented) An isolated antibody or fragment thereof that specifically binds an ICE-LAP 3 protein purified from a cell culture wherein said ICE-LAP 3 protein is encoded by a polynucleotide encoding amino acids 1 to 303 of SEQ ID NO:2 operably associated with a regulatory sequence that controls the expression of said polynucleotide.

99. (Currently amended) The antibody or fragment thereof of claim 98 ~~which~~ wherein the antibody is a monoclonal antibody.

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100. (Currently amended) The antibody or fragment thereof of claim 98 ~~which wherein the antibody~~ is a human antibody.

101. (Previously presented) The antibody or fragment thereof of claim 98 which is selected from the group consisting of:

- (a) a chimeric antibody;
- (b) a polyclonal antibody;
- (c) a humanized antibody;
- (d) a single chain antibody; and
- (e) an Fab fragment.

102. (Previously presented) The antibody or fragment thereof of claim 98 wherein said antibody or fragment thereof specifically binds to said protein in an ELISA.

103. (Previously presented) An isolated antibody or fragment thereof that specifically binds an ICE-LAP 4 protein purified from a cell culture wherein said ICE-LAP 4 protein is encoded by a polynucleotide encoding amino acids 1 to 277 of SEQ ID NO:4 operably associated with a regulatory sequence that controls the expression of said polynucleotide.

104. (Currently amended) The antibody or fragment thereof of claim 103 ~~which wherein the antibody~~ is a monoclonal antibody.

105. (Previously presented) The antibody or fragment thereof of claim 103 ~~which wherein the antibody~~ is a human antibody.

106. (Previously presented) The antibody or fragment thereof of claim 103 which is selected from the group consisting of:

- (a) a chimeric antibody;
- (b) a polyclonal antibody;
- (c) a humanized antibody;
- (d) a single chain antibody; and
- (e) an Fab fragment.

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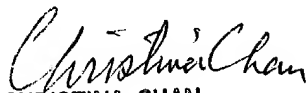
107. (Previously presented) The antibody or fragment thereof of claim 103 wherein said antibody or fragment thereof specifically binds to said protein in an ELISA.
4. Claims 31-35, 40-57, 62-68, 73-91 and 96-107 are pending and are allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
6. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

January 12, 2004


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